

REMARKS

Claims 1-17 and 21-30 have been rejected. Claims 1-5, 7-8, and 26-30 have been cancelled without prejudice to consideration in a continuing application. Claims 6, 9, and 21-23 have been amended. Reconsideration of the present application, as amended, is respectfully requested in view of the following comments.

Claims 1, 7, 8, 23, 26, 29, and 30 were rejected as being anticipated by U.S. Patent 5,354,305 to Lewis, Jr. et al. (Lewis). While this rejection is respectfully traversed, claims 1-5, 7, 8, and 26-30 have been cancelled and dependent claim 23 has been amended to depend from claim 16 to expedite prosecution of the present application. Thus, it is believed this ground of rejection is moot.

Claim 6 was rejected as being unpatentable over the Lewis reference stating that since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. This claim has been amended to depend from claim 16. To the extent the rejection is maintained against claim 6 as amended, it is traversed based upon at least the reasons given in connection with this rejection in the prior office action.

Claims 2-5, 9, 21, 22, 27, and 28 were rejected under 35 USC §103 as being unpatentable over the Lewis reference in view of U.S. Patent No. 5,620,449 to Faccoili et al. While the applicant respectfully traverses, claims 2-5, 27 and 28 have been cancelled and claims 21 and 22 have been amended to depend from claim 16 to expedite prosecution. Thus, it is believed that this aspect of the rejection is rendered moot.

Claims 16 and 17 were rejected under 35 USC §103 as being unpatentable over the Lewis reference in view of Faccioli, in view of U.S. Patent No. 4,788,847 to Sterghos. The applicant respectfully traverses. The Office Action rejects these claims stating "the above combination of references [Lewis and Faccioli] did teach a bending device, but fail to teach a bending device jaw structure..." at the bottom of page 4. In the prior rejection, the Office Action relies on Faccioli to "evidence the use of a bending nail" citing column 3, lines 35-61 and column 6, lines 55-65. This citation fails to teach any type of "bending device" as asserted in the claim 16 rejection. Indeed, a nail may be bent by hand or in other ways besides with a device including the features recited in claim 16.

Faccioli is directed to a post-implant process of blind-hole drilling after nail 13 is implanted in the bone. The nail shape is determined long before this stage. Lewis is singularly focused on the application of a repair device for nerves. Nerve tissue and bone tissue differ in a number of respects. For instance, "when reconnection of the nerves is attempted, a tensile force may be created in the severance as they are drawn together, complicating both the process of rejoining the severed ends, and the healing process." (See Lewis, column 1, lines 27-32). Furthermore, nerve tissue is generally soft and subject to displacement as compared to the relatively rigid and hard outer portion of a bone. In contrast to the tensile forces to which severed nerve tissue is generally exposed, a long bone, such as the femur, "is a major load-supporting bone which, in use, is subjected to substantial axially-directed compressive loading and is subjected to frequent and substantial torsional loading." (See U.S. Patent 4,862,883 to Freeland, column 1, lines 60-63, which was asserted in the prior Office Action).

To modify repair device 10 of Lewis by bending would undermine its operation as an apparatus for joining elastic nerves under tensile forces. Picture, for example, a bend in device 10 while inside the nerve as shown in Fig. 8. For this soft tissue under tension, a bent implant would likely induce stresses that tend to pull open the nerve parts abutted at 48, and/or would increase tearing and insult to internal tissue of the nerve in trying to implant device 10 in a manner that does not pull open the abutted ends at 48.

"If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." Manual of Patent Examining Procedure (MPEP) §2143.01. MPEP §2143.01 also states that "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." Likewise, there must be some reasonable expectation of success with regard to the asserted combination. MPEP §2143.02. Thus, it is asserted that the proposed combination of Lewis and Faccioli is improper - failing to teach a "bending device" as asserted in connection with the rejection of claim 16.

The addition of the Sterghos reference does nothing to cure such deficiencies. In fact, the complicated device of this reference is directed to rod bending by way of a powered hydraulic system, which is antithetical to its use as a tool for surgical rods of the dimensions discussed in Faccioli. Correspondingly, the Sterghos reference is nonanalogous art relative the field of the invention.

Besides the patentability of the base claim 16, additional reasons support patentability corresponding dependent claims. For example, none of the references teach a bending device

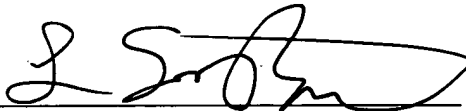
with a pair of manually operable handles coupled to the jaw as recited in claim 17. In another example, reference to a 9 mm nail in column 5, lines 19-26 of Faccioli tends to lead away from the 4-7 mm range recited in claim 22. In still another example, claim 9 as amended now depends from claim 16, and recites fasteners each with a threaded distal tip, a threaded proximal shank, and an unthreaded portion between these. None of the references teach or suggest such features. Thus numerous further reasons support patentability claims depending from claim 16.

Claims 10-15, 24, and 25 were rejected as being unpatentable over Faccioli in view of Lewis. This rejection is traversed. As pointed out in the Office Action, Faccioli describes nails that are bent. Those skilled in the art would be discouraged from considering the Lewis reference as a source of modification because effectiveness of its nerve repair device is undermined by bending. Moreover, using the flattened parts of Lewis contended to have greater cross-section dimension do not appear compatible with the tooling of Faccioli's drilling jig -- such as locking rod 21; where the blind-hole drilling capability of such equipment is the main initiative of Faccioli in the first place. Thus, the rejection of claims 10-15, 24, and 25 based on the Faccioli/Lewis combination is also improper.

Further reasons also support patentability of claims depending from claim 10. For instance, claim 11 recites that the central section is curved and laterally bending the proximal area with an acute angle. This central section curve and acute angle at the proximal area are not taught or suggested by any of the asserted references. Claim 12, further defines claim 11 to include the untaught feature of bending the distal area at an acute angle. Moreover, the features defined in dependent claim 15 are absent. Thus, many reasons support patentability of dependent claims.

In view of the foregoing, it is believed that claims 6, 9-17, and 21-25 are in condition for allowance. Reconsideration of the present application as amended is respectfully requested. The Examiner is encouraged to contact the undersigned by telephone to respond to any outstanding matters concerning the present application.

Respectfully submitted,

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